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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HFI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

December 10, 1999

VIA FEDERAL EXPRESS

Victor A. Shull, Vice President
Vitalabs, Inc.
9696 Tara Boulevard
Jonesboro, GA 30238

Warning Letter
(99-ATL-15)

Dear Mr. Shull:

During an inspection of your firm on May 12 & 14, 1999, an FDA investigator collected a sample of *CHELATED MEGA MIN HIGH POTENCY MINERAL TAB* (100 tablets/bottle) which you distribute under the Vitalabs, Inc. brand name. Analysis of this product by the Atlanta Center for Nutritional Analysis (ACNA) revealed that it is subpotent for calcium. Results obtained are as follows:

Found	Declared	% Declared	
672 mg/2 tabs.	1000 mg/2 tabs.	67.2	Original analysis
499 mg/2 tabs.	1000 mg/tabs.	49.9	Check analysis

The above results cause the subject product to be misbranded within the meaning of section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) in that its labeling is false or misleading in any particular, i.e., the serving declaration for calcium is false.

During a telephone conversation with Carlos Bonnin, Compliance Officer, on August 23, 1999, you explained that the tablets inside the containers we sampled and tested were not the labeled product. Instead, you claimed that the problem originated when a different product was repacked and erroneously labeled as *CHELATED MEGA MIN HIGH POTENCY MINERAL TAB*, by an employee that no longer works for your firm. Based on the information you provided Mr. Bonnin on August 23, 1999, and on September 8, 1999, the product in question appears to be further misbranded within the meaning of section 403(i)(2) in that it contains ingredients that are not listed on the label.

As a repacker and distributor of dietary supplements, you are responsible for ensuring not only that the products you repack and/or distribute are safe for human consumption, but that they are also labeled in accordance with current labeling regulations.

Please notify this office, in writing, within three (3) weeks of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If you continue to distribute dietary supplements that are adulterated and misbranded as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Your written reply should be directed to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309.

Sincerely,

Ballard H. Graham, Director
Atlanta District